Washington University in St. Louis
James McKelvey School of Engineering

A Novel Bandage System

Verification & Validation Report

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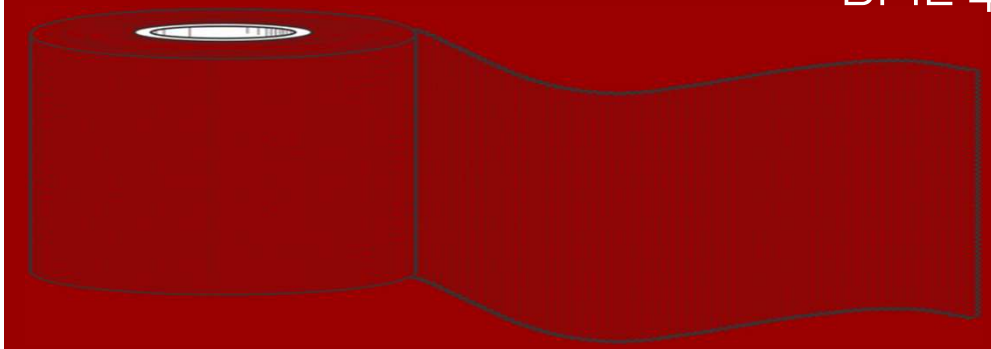
Group 15
BME 401A



No modifications to need statement or project scope

There is a need for a wound analysis and care system by clinicians to capture chronic stage 2-3 wound morphology and generate in a timely manner waste-reducing custom bandages.

- Portable imaging device that can be connected to a computer to record and save images of the wound in a digital file
- Software to analyze the wound from the images, quantify and model the interior surface of the wound, and create a physical product embodying the size and shape of a custom bandage

Design Specifications - Modifications

Image Brightness
The wound image being analyzed should have a 200:1 contrast ratio or greater in order to be compatible with the software.

Image Brightness
The wound image should be taken in standard natural or indoor lighting; it should not be dark or obscured by excess shadow.

→ Software does not require a numerical threshold but image needs to be taken in a setting with light so there is enough contrast

Design Specifications - Modifications

Template Options
A minimum of 3 different template options are generated by the software for each wound image that is processed.

Template Options
A simple and a more complex template are generated by the software for each wound image that is processed.

→ We want to prioritize integrating the entire process, not one specific wound analysis component… time permitting, we will work on progressive levels of tessellation, but right now that is not our main focus

Updated Team Responsibilities/Gantt Chart

→ Victoria will lead the development of testing models task

Victoria

Yushin

Hannah

Verification Plan

Product Usability

Relevant design specs: size and ease of use of imaging device, complexity of software, skill level of software user

- Make sure someone with 12-cm grip can hold point-and-shoot camera with one hand and comfortably take pictures from different angles
  - Grip = tip of middle finger to bottom lateral crease of palm
  - Team members can already do this but have larger than 12-cm grips
- Train 5 people (3 peers, 2 adults) in different fields with no knowledge of project to use software
  - 20 minutes training
  - Make sure they can use software and export template design without any assistance

Wound Characteristics

Relevant design specs: wound size, wound severity, image resolution, image brightness

- Will use 3D-printed objects (non-wound models) and artificial skin stage 2-3 wound models

- Chosen camera indicates better than 1 megapixel resolution
  - Will verify each image that is taken for all tests
- Brightness specification no longer numerical... just needs to be in light setting (no darkness or excessive shadows)
  - Will test in natural light and indoor light

Software Capabilities

Relevant design specs: measurement accuracy, processing time, template options

- Template options generated by software and displayed in user interface
- Processing time seems to not be an issue based on preliminary tests
    - Will continue timing it for every trial to make sure < 30 minutes

- 3D-printed model will be dimensionalized in AutoCAD so surface area of interior can be calculated
- One artificial skin wound model will be made from polygonal extrusions so can make measurements with calipers to calculate the surface area
- Software reconstructs wound so surface area can be computed
- Will compare values to test accuracy

Means of Production

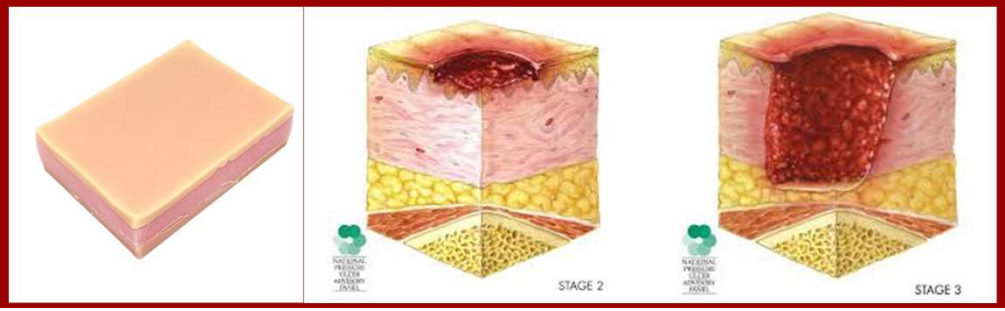
Relevant design specs: production time, sterility, power source

- Laser cutter plugs into wall outlet so meets power source requirement
- Production time for laser cutter jobs of our shape and size does not seem to be an issue (order of minutes rather than hours)
    - Will record timing for every trial to make sure < 3 hours
- Sterilization cannot be implemented because we are using Makerspace equipment for proof-of-concept
    - If we could, we would implement hydrogen peroxide gas plasma

Validation Plan

Applicability to Chronic Wounds

- First and foremost the software is intended to improve chronic wound care, so it has to be applicable to chronic wounds
- We need to be able to take pictures from multiple angles of a chronic wound and calibrate the camera
  - Using open source images online or patient data is not possible
  - We are creating a wound model out of artificial skin based on the description and diagram of a stage 2-3 pressure ulcer



Integration of Wound Analysis with Bandage Production

- As previously emphasized, there is a lack of integration of wound analysis with bandage production
- We will demonstrate with a video that our software integrates these things so not only is the wound analyzed but it is also being used to directly generate a template that can be sent to a laser cutter in an streamlined way

Bandage Cutting

- For clinical relevance, the patient should get an individualized bandage
- We are not focused on the bandage itself, so we are using 100% cotton fabric as our "bandage"
- By cutting the fabric, we will demonstrate how the process would be applicable to actual bandages and bandage material

FDA Approval Process

Software as a Medical Device (SaMD) = “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”

→ Our system would likely be classified as category II

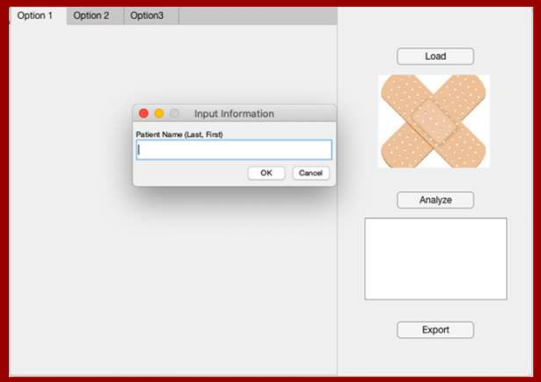
→ Approval pathway: prove valid clinical association, demonstrate technical accuracy and reliability, and show how clinically meaningful

Companies developing digital health products can apply for FDA’s precertification program to make approval process more efficient

Overall Progress and Proof-of-Concept Testing

- Makerspace laser cutter training and fabric testing completed
  - Successful trials cutting fabric into regular and irregular shapes

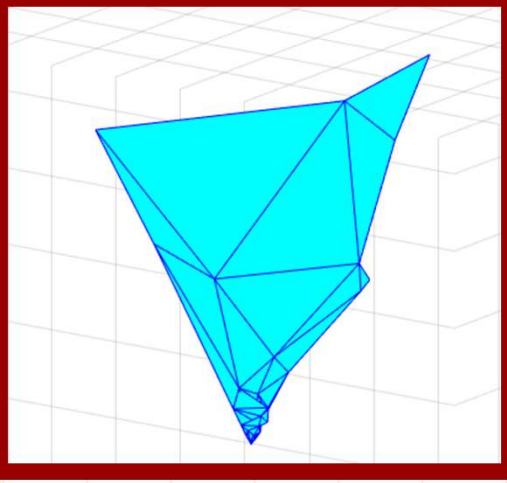
- User interface framework completed in Matlab's app designer
  - Load and export push-buttons are functional
  - Will update as continue to work on analytical software

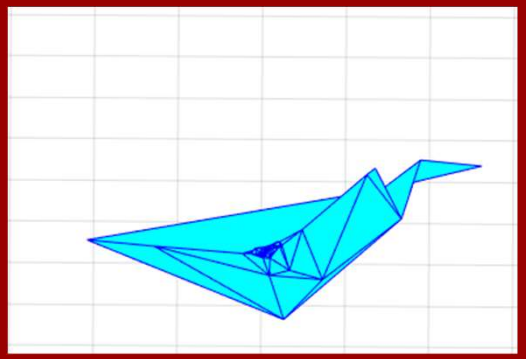


Overall Progress and Proof-Of-Concept Testing

- Analytical software
  - Structure from motion implemented to produce 3D point cloud
  - Triangulation used to map surface
  - Working on iso2mesh and edge detection algorithms as well

- Preliminary testing w/ various objects
  - 5-10 pictures taken
  - Larger objects with more distinct shapes work better
  - Triangulation affects morphology





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Questions?